Remarks/Arguments

Applicants thank the Examiner for careful consideration of the application.

Claims 1-72 are pending in the Application.

Please amend claims 1, 3, 10-16, 18, 20, 23, 25, and 54.

Please cancel claim 9.

No claims have been allowed by the Examiner.

I. Election/Restriction:

Applicants elected after restriction, Group 1, claims 1-20, 23, 24, 27, and 54 with traverse. Applicant's election with traverse of Examiner's restriction requirement has been acknowledged by Examiner. Examiner after reconsideration has made the restriction requirement Final. Applicants believe that the restriction requirement is improper.

Examiner has required election of a single group. Therefore, Applicants withdraw from consideration claims 21-22 and 25-26 pending allowance of an independent claim from which they depend. Applicants will be entitled to consideration of these withdrawn claims to additional groups that are dependent upon an allowed independent claim. In addition, Applicants cancel claims 28-53 and 55-72 without prejudice, and their content reserved for inclusion in a continuation/divisional application.

II. REJECTIONS UNDER 35 U.S.C. §103(a)

Examiner has rejected claims1-20, 23, 24, 27, and 54, under 35 U.S.C. § 103(a) as being unpatentable over Carden, Jr. et al. (US 6086942, "Carden") in view of Stewart (WO 95/01735, "Stewart"). This rejection is respectfully traversed with regard to claims 1-20, 23, 24, 27, and 54 since neither of the cited references, taken either individually, or in combination therewith, teach, suggest, or mention the claimed invention.

To establish a prima facie case of obviousness, three basic criteria must be met. There must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, i.e. the prior art must suggest the desirability of the claimed invention. There must be a reasonable expectation of success. MPEP §2143. These requirements are not met here. In addition, to establish *prima facie* obviousness of a claimed invention, all claim limitations must be taught or suggested by the prior art. MPEP 2143.03 (*citing In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)).

In regards to amended independent claim 1, amended independent claim 1 discloses "activating a fluid ejector to eject at least one drop of a bioactive fluid; dispensing the bioactive fluid in a two-dimensional array onto the ingestible sheet; and forming an array of bioactive deposits on the ingestible sheet," as it is disclosed, defined, and claimed, in amended independent claim 1 by Applicants in the instant specification. In contrast, Carden teaches "drops of material are discretely applied to a surface of a support element of a brachytherapy source . . . [where] the fluid may be radioactive or it may be a precursor material that is activated by nuclear particle bombardment." Col. 7, lines 54-58. In addition, Carden discloses "[r]adioactive fluid is printed on the inner tube at printing station 025, the fluid is cured at curing station 026, the activity of the printed tube is measured at

radiation, measuring station 027 . . ." Col. 9, lines 15-19. Carden further discloses '[p]rinting fluids suitable for use in embodiments of the present invention for printing radioactive or precursor materials with a fluid-jet printhead comprise either a radioactive isotope or a precursor isotope, a carrier solvent that may be a blend of solvents and additives, together with a binder." Col. 14, lines 10-14. In Column 14, lines 15-39, Carden discusses various radioactive isotopes such as Pd-103 or I-125 or precursor isotopes "suitable for use in a fluid of the present invention." These compounds are all metal salts, complexes or compounds containing generally a transition metal or halogen salt that is either radioactive or can be made radioactive by bombardment with suitable nuclear particles (e.g. neutron radiation). *See* Col. 4, lines 35-36 describing bombardment. Thus, Carden discloses a brachytherapy source formed by depositing either a radioactive material or a precursor material, activated by nuclear particle bombardment, on a substrate." Carden does not disclose, teach, or suggest dispensing a bioactive fluid in a two-dimensional array onto an ingestible sheet; and forming an array of bioactive deposits on the ingestible sheet.

Further, Stewart, does not disclose, teach, or suggest "activating a fluid ejector to eject at least one drop of a bioactive fluid; dispensing the bioactive fluid in a two-dimensional array onto the ingestible sheet; and forming an array of bioactive deposits on the ingestible sheet." In contrast, Stewart teaches "a reinforced edible film 16 composed of an edible film 18 which is releasably attached to a flexible substrate 20 (see Figure 5). The edible film has been cut and the edible film printed upon to provide the decorations 10a, 10b depicted in Figure 1," for decorating foodstuffs. Page 9, bottom paragraph. In addition, Stewart discloses "[i]t is also possible for sheets of reinforced edible film 16 as depicted in Figure 10 to be utilized by printing facilities to produce generic and/or personalized printing upon the edible film 18. The printing may include special messages, pictures and/or drawings . . . [In addition] any printing machine and printing method for creating decorations, *provided, of course, edible inks are used*." Page 18 (bottom) to

page 19 (top); (emphasis added). Stewart further discloses "[t]he edible film may be placed into conventional printing presses, pen plotters, ink jet printers . . . etc." Page 20, paragraph 7. And, Stewart discloses "the term "marking" is to be understood to mean causing any kind of indicia [i.e. distinctive mark] to be placed upon the edible film, such as, for example, by printing, writing, drawing . . . and may include causing selected additives in the edible film solution to produce patterns [i.e. marks with a design] in the dried edible film." Page 22, top paragraph. Thus, Stewart teaches a method of decorating foodstuffs utilizing an edible sheet having visible printing, writing, drawing, or pictures formed on the edible sheet using an edible ink. Stewart does not disclose, teach, or suggest "activating a fluid ejector to eject at least one drop of a bioactive fluid; dispensing the bioactive fluid in a two-dimensional array onto the ingestible sheet; and forming an array of bioactive deposits on the ingestible sheet." In addition, Stewart does not disclose, teach, or suggest depositing material on an edible sheet that would not be readily visible. The present invention, however, does not require visibility of the bioactive deposits formed on the ingestible sheet. The combination of Carden and Stewart are silent on "activating a fluid ejector to eject at least one drop of a bioactive fluid; dispensing the bioactive fluid in a two-dimensional array onto the ingestible sheet; and forming an array of bioactive deposits on the ingestible sheet." Thus, the Examiner's suggested combination of Carden and Stewart does not teach the present invention as recited in amended independent claim 1, and thus, does not establish *prima facie* obviousness of the claimed invention, since not all claim limitations are taught or suggested by the prior art under MPEP §2143. Accordingly, Applicants assert that the rejection has been overcome. Therefore, Applicants respectfully request that the Examiner withdraw the rejection of amended independent claim 1 based on Carden in view of Stewart under 35 U.S.C. § 103(a).

In addition, if the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. MPEP

§2143.01 (citing *In re Gordon*, F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)). In regards to amended independent claim 1, claim 1 is written to a method of manufacturing a bioactive fluid dose by dispensing the bioactive fluid in a two-dimensional array onto an ingestible sheet; and *forming an array of bioactive deposits on the ingestible sheet. Emphasis added.* Carden, on the other hand teaches, a brachytherapy source formed by depositing either a radioactive material or a precursor material, which is activated by nuclear particle bombardment, on a substrate. In addition, Carden teaches that "*localized treatment of tumors* and other medical conditions by the *interstitial implantation of radioactive materials* is a recognized treatment modality of long standing. Radioactive implants are used to provide radiation therapy in order to destroy tumors . . . to prevent the growth of microscopic metastatic deposits . . . [and] to irradiate the postoperative tumor bed . . . . *Implantation of radioactive sources directly into solid tumors* . . . is . . . referred to as brachytherapy." Col. 1, lines 35-47 (emphasis added).

Carden teaches "[a] preferred embodiment of the device of the present invention is a brachytherapy source, or "seed" . . . used as a permanent implant. Clinically, several such seeds are *inserted interstitially in* and around *a tumor* to produce a radiation field, which decays away with the half life of the radioactive isotope. For example, in the case of Pd-103 the half-life is 17 days and in the case of I-125 it is 60 days." Col. 12, lines 19-31(emphasis added). Carden also teaches generally the use of metal i.e. titanium tubes, rods, or sheets as the substrate material. *See e.g.* Col. 10, lines 10-11 (titanium tube 103 is mounted between driven spindle 102 and free-spindle 104); *also see* Col. 10, line 61 (al flat titanium metal foil); *see* Col. 16, lines 12-13 (an outer tube that is welded to the inner tube at the ends); *see* Col. 17, line 42 (hollow-tube seed device such as that disclosed in the '828 patent (i.e. titanium tube); *see* Col. 18, lines 35-36 (If an inner tube of the '828 patent (i.e. titanium tube). Even where Carden teaches the use of a non-metal substrate Carden places the limitation that the "radioactive strand . . . can be made either of a permanent plastic or a biodegradable plastic. In the latter

embodiment, after the radioactive isotope decays to a biologically acceptable level (i.e. after days in the body), the strand is dissolved by the body." Col. 20, lines 32-38. From this analysis the proposed modification, of combining the teachings of Carden with that of Stewart, would render the prior art invention being modified unsatisfactory for its intended purpose without further modification. Carden teaches welding of an outer metal tube to an inner titanium tube to provide protection of the radioactive material dispensed on the titanium tube. Carden also teaches coating of the radioactive material to provide such protection. However, utilization of an ingestible sheet would render welding inoperable, and utilization of a coating would provide an avenue of attack of body fluids to the ends of the ingestible sheet. Carden teaches that preferably the brachytherapy devices "have a . . . sealing element to seal the surface of the . . . support element and to *prevent any release or escape of radioactive material from the device when in use*." Col. 4, line 66 to Col. 5, line 2 (emphasis added). Thus, in teaching welding or coating Carden does not teach or suggest encapsulating the substrate, which may be necessary for proper functioning of radioactive material deposited on typical ingestible sheet materials inserted within a body. That is, the properties of a substrate to be utilized for implantation into a body (i.e. biodegradable) versus the properties of a substrate to be ingested (i.e. ingestible) are generally different. Applicants respectfully disagree with Examiner's logic that the printing of a radioactive fluid on a metal sheet or tube, or plastic strand that is later *used in the body* in combination with printing of an edible ink on an edible sheet teaches, suggests or provides motivation to make the proposed modification since Stewart in utilizing an edible film is silent on utilizing any biologically active material and Carden is silent on utilizing ingestible materials. Applicants respectfully suggest that Examiner is improperly utilizing Applicants' disclosure as a template in which to find the teachings of the prior art so that the Applicants' invention is rendered obvious. Thus, there is no suggestion or motivation to make the proposed modification. In addition, if the proposed modification or combination of the prior art would change the principle of operation of the

prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. MPEP 2143.01 (*citing In re Ratti* 270 F.2d 810, 123 USPQ 349 (CCPA 1959). Based on the above analysis, Applicants respectfully disagree with Examiner's statement that "it would be obvious to print a bioactive fluid on an edible or ingestible sheet or substrate." Thus, the Examiner's suggested combination of Carden and Stewart does not meet at least two of the three basic criteria that must be met to establish a prima facie case of obviousness under MPEP §2143. Accordingly, the Applicants assert that the rejection has been overcome

In addition, a reasonable expectation of success in adapting the prior art of Carden to the utilization of an edible sheet disclosed in Stewart is also absent given the general knowledge in the field at the time the present invention was disclosed, defined, and claimed in amended independent claim 1. As noted above such a combination either will be inoperable or it would require further invention to be made operable. Carden in teaching coating of the radioactive material to provide sealing does not disclose, teach, or suggest encapsulating the substrate. Generally when describing coating a sheet one of ordinary skill in the art would not interpret such teaching as including coating of all edges and the opposite side of the sheet. One of ordinary skill in the art would use the term encapsulating to refer to such a process. Stewart on the other hand is silent on coating or encapsulating the edible ink deposited onto the edible sheet. Thus, in combining the teachings of Carden and Stewart the brachytherapy tube made utilizing an ingestible sheet would provide no expectation of success since as noted above it would render the prior art invention being modified unsatisfactory. In addition, although Carden is silent on the radiation properties of the substrate Carden does note that the "radiation-attenuating characteristics of the substrate" are measured. Col. 3, lines 17-19. Carden also discloses that a "binder suitable for use in a fluid of the present invention has the following properties: a) it is sufficiently *radiation resistant* so that the absorbed radiation does not alter the properties of the binder enough to prevent reliable printing or *compromise the*

desired end user properties . . . ." Col. 14, line 66 to Col.15, line 3 (emphasis added). Further, Carden teaches "the sealing layer used is capable of retaining its physical properties when exposed to the radiation environment associated with activation and is not itself activated to form significant amounts of any isotopes . . . ." Col 9, lines 36-40. Finally, Carden discloses that the radioactive fluid has a high radiation intensity. Col. 5, lines 22-23. Thus, Applicants assert there is little if any expectation of success in adapting the prior art of Carden to the utilization of an edible sheet disclosed in Stewart. Thus, the Examiner's suggested combination of Carden and Stewart does not teach the present invention as recited in amended independent claim 1 and thus does not meet any of the three basic criteria that must be met to establish a prima facie case of obviousness under MPEP §2143. Accordingly, the Applicants assert that the rejection has been overcome. Therefore, Applicants respectfully request that the Examiner withdraw the rejection of amended independent claim 1 based on Carden in view of Stewart under 35 U.S.C. § 103(a).

In regards to amended independent claim 54, amended independent claim 54 discloses "inserting a fluid ejection cartridge into a bioactive fluid dispensing system, said cartridge containing a mixture of an ingestible ink and a bioactive fluid in a reservoir forming a printable bioactive fluid; . . . specifying a user message; and printing said user message on the ingestible sheet using said printable bioactive fluid," as it is disclosed, defined, and claimed, in amended independent claim 1 by Applicants in the instant specification. As discussed above Carden discloses a brachytherapy source formed by depositing either a radioactive material or a precursor material, activated by nuclear particle bombardment, on a substrate." Carden does not disclose, teach, or suggest a mixture of an ingestible ink and a bioactive fluid in a reservoir forming a printable bioactive fluid; specifying a user message; and printing said user message on an ingestible sheet using said printable bioactive fluid.

Further, Stewart, does not disclose, teach, or suggest, "inserting a fluid ejection cartridge into a bioactive fluid dispensing system, said cartridge containing a mixture of an ingestible ink and a bioactive fluid in a reservoir forming a printable bioactive fluid; . . . specifying a user message; and printing said user message on the ingestible sheet using said printable bioactive fluid." As discussed above Stewart teaches a method of decorating foodstuffs utilizing an edible sheet having visible printing, writing, drawing, or pictures formed on the edible sheet using an edible ink. Stewart does not disclose, teach, or suggest a fluid ejection "cartridge containing a mixture of an ingestible ink and a bioactive fluid in a reservoir forming a printable bioactive fluid; and printing said user message on the ingestible sheet using said printable bioactive fluid." The combination of Carden and Stewart are silent on "inserting a fluid ejection cartridge into a bioactive fluid dispensing system, said cartridge containing a mixture of an ingestible ink and a bioactive fluid in a reservoir forming a printable bioactive fluid; . . . specifying a user message; and printing said user message on the ingestible sheet using said printable bioactive fluid." Thus, the Examiner's suggested combination of Carden and Stewart does not teach the present invention as recited in amended independent claim 54, and thus, does not establish *prima facie* obviousness of the claimed invention, since not all claim limitations are taught or suggested by the prior art under MPEP §2143. Accordingly, Applicants assert that the rejection has been overcome. Therefore, Applicants respectfully request that the Examiner withdraw the rejection of amended independent claim 54 based on Carden in view of Stewart under 35 U.S.C. § 103(a).

In regards to dependent claims 2-20, 23, 24, and 27, if an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. MPEP 2143.03. Dependent claims 2-20, 23, 24, and 27 are dependent upon amended independent claim 1, and are therefore believed to be allowable as dependent upon a believed allowable claim. Accordingly, Applicants assert that the rejection has been overcome.

Therefore, Applicants respectfully request that the Examiner withdraw the rejection of dependent claims 2-20, 23, 24, and 27 under 35 U.S.C. § 103(a).

In regards to amended dependent claims 10-15, amended dependent claims 10-15 disclose various dosage forms:

10. "a dosage form . . . wherein the density of the bioactive deposits varies . . . whereby a gradient in a bioactive agent is formed;"
11. "wherein after being ingested the amount of the bioactive agent released increases over time;"
12. "decreases over time;"
13. "the amount of the bioactive agent released remains constant over time;"
14. "a discrete amount of the bioactive agent is released in a repeatable manner over time;" and
15. "a discrete amount of the bioactive agent is released over different times,"

as it is disclosed, defined, and claimed, in amended dependent claims 10-15 by Applicants in the instant specification. In contrast, as previously discussed above, Carden discloses a brachytherapy source formed by depositing either a radioactive material or a precursor material, activated by nuclear particle bombardment, on a substrate. Further, as previously discussed above, Stewart teaches a method of decorating foodstuffs utilizing an edible sheet having visible printing, writing, drawing, or pictures formed on the edible sheet using an edible ink. In addition, Examiner's own statement admits "neither reference teaches the gradient composition recited in . . . claims 9-15" of the instant specification. Thus, the Examiner's suggested combination of Carden and Stewart does not teach the present invention as recited in dependent claims 10-15, and thus, does not establish *prima facie* obviousness of the claimed invention, since not all claim limitations are taught or suggested by the prior art under MPEP §2143. Accordingly, Applicants assert that the rejection has been overcome. Therefore, Applicants respectfully request that

the Examiner withdraw the rejection of dependent claims 10-15 based on Carden in view of Stewart under 35 U.S.C. § 103(a).

Therefore, in view of the foregoing Amendment and Remarks, Applicants believe the present application to be in a condition suitable for allowance. Examiner is respectfully urged to withdraw the rejections, reconsider the present Application in light of the foregoing Amendment, and pass the amended Application to allowance.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is respectfully requested to call Applicants' representative at (541) 715-1694 to discuss the steps necessary for placing the application in condition for allowance.

Favorable action by the Examiner is solicited.

Hewlett-Packard Company
1000 NE Circle Blvd. m/s 422B
Corvallis, OR 97330
(541) 715-1694

Respectfully submitted,
Brian Craig Lee, et al.

By: Donald J. Coulman
Donald J. Coulman
Reg. No. 50,406
Agent for Applicant